UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES, et al. ex rel.
OSWALD BILOTTA,

Plaintiffs and Relator,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

ORDER

11 Civ. 0071 (PGG)

PAUL G. GARDEPHE, U.S.D.J.:

In this qui tam action, Relator Oswald Bilotta – a former Novartis sales representative – alleges that Defendant Novartis Pharmaceuticals Corporation ("Novartis") violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B), and related state laws by (1) causing false claims for reimbursement of patient prescriptions – which were allegedly written in exchange for kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and related state laws – to be submitted to federal and state health care programs, and (2) promoting the drug Valturna for off-label use, thereby causing the submission of false claims to federal and state health care programs. The United States (the "Government") and the State of New York have intervened as to the kickback claims.

The parties have submitted letters regarding a discovery dispute as to whether Novartis should be required to produce documents and data regarding (1) speaker program events related to the ten Novartis drugs at issue in this case, and (2) prescriptions written for these ten drugs between January 1, 2001 and December 31, 2014.

BACKGROUND

The Amended Complaint alleges that from January 2002 through at least November 2011 Novartis systematically bribed doctors to induce them to write prescriptions for Novartis drugs. See U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 1, 66. Those drugs include Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valturna, Tekamlo, and Starlix. See id. ¶ 66. The Government alleges that Novartis induced doctors to prescribe its drugs primarily through the use of "sham" speaker events. (Id. ¶¶ 1-3) Although the Amended Complaint alleges that this misconduct continued through "at least" November 2011, the Amended Complaint contains no allegations suggesting that the conduct continued after November 2011. The Amended Complaint likewise contains no allegations suggesting that similar conduct took place prior to January 1, 2002.

In a 2010 settlement with Novartis, the Government and several states released claims concerning three Novartis drugs – Diovan, Tekturna, and Exforge – through December 31, 2009 (the "2010 Settlement Agreement"). (Id. ¶¶ 63, 172) Accordingly, the only claims related to those drugs that remain at issue are those that arise from conduct that occurred after December 31, 2009. See id. ¶ 173. The Amended Complaint states, however, that the Government is pursuing claims for the so-called "HCT variants" of these drugs for the entire time period alleged in the Amended Complaint. See id. ¶ 172.

On June 19, 2015, the Government submitted a letter regarding an anticipated motion to compel. The Government seeks nationwide speaker program data related to the ten Novartis drugs at issue in this case, including dates, locations, and topics of events; names of doctors; and amounts spent on events and honoraria. See June 19, 2015 Gov't Ltr. (Dkt. No. 126) at 2. The Government also seeks prescription-writing data acquired by Novartis relating to

the ten drugs at issue, including the prescribing doctors' names, the drugs prescribed, and the dates of the prescriptions. (Id.) As to both of these requests, the Government seeks data for the time period between January 1, 2001 and December 31, 2014. (Id.)

In response to the Government's discovery requests, Novartis has produced (1) data for Lotrel, Valturna, and Starlix for the time period from January 1, 2002 to November 30, 2011, and (2) data for the remaining seven drugs for the time period between January 1, 2010 and November 30, 2011. (Id.) Novartis argues that it is not obligated to produce information as to any of the drugs for the time period before and after the events alleged in the Amended Complaint – i.e., data from before 2002 and after November 2011 – because this information is not relevant to the Government's claims. See June 24, 2015 Novartis Ltr. at 1-4. Novartis also argues that the 2010 Settlement Agreement precludes discovery of the requested information for Diovan, Tekturna, Exforge, or any of their HTC variants for 2002 through 2009 (the "Release Period"). See id. at 4-5.

DISCUSSION

I. LEGAL STANDARD

Rule 26(b)(1) of the Federal Rules of Civil Procedure provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense" and that "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. 26(b)(1). "This obviously broad rule is liberally construed." Daval Steel Prods. v. M/V Fakredine, 951 F.2d 1357, 1367 (2d Cir. 1991). "Nevertheless, discovery is not boundless, and a court may place limits on discovery demands that are 'unreasonably cumulative or duplicative,' or in cases 'where the burden or expense of the proposed discovery outweighs its likely

benefit.'" Kingsway Fin. Servs., Inc. v. Pricewaterhouse-Coopers LLP, No. 3 Civ. 5560 (RMB) (HBP), 2008 WL 4452134, at *4 (S.D.N.Y. Oct. 2, 2008) (quoting Fed. R. Civ. P. 26(b)(2)(C)(i), (iii)).

Courts also have "the authority to confine discovery to the claims and defenses asserted in the pleadings, and . . . the parties . . . have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings." Fed. R. Civ. P. 26(b)(1) Advisory Committee Note – 2000 Amendments. "Accordingly, discovery 'may not be used as a fishing expedition to discover additional instances of wrongdoing beyond those already alleged.'" Barbara v. MarineMax, Inc., No. 12 Civ. 368 (ARR) (RER), 2013 WL 1952308, at *2 (E.D.N.Y. May 13, 2013) (quoting Wells Fargo Bank N.A. v. Konover, No. 5 Civ. 1924 (CFD) (WIG), 2009 WL 585430, at *5 (D. Conn. Mar. 4, 2009)); see also Tottenham v. Trans World Gaming Corp., No. 00 Civ. 7697 (WK), 2002 WL 1967023, at *2 (S.D.N.Y. June 21, 2002) ("Discovery, however, is not intended to be a fishing expedition, but rather is meant to allow parties to flesh out allegations for which they initially have at least a modicum of objective support." (quotation marks and citation omitted)).

II. ANALYSIS

A. Discovery of Data from the 2002-2009 Release Period

Novartis argues that the 2010 Settlement Agreement precludes discovery of the requested information as to Diovan, Tekturna, Exforge, or any of their HTC variants for the period between 2002 and 2009. See June 24, 2015 Novartis Ltr. at 4-5.

The 2010 Settlement Agreement states that

> the United States . . . releases [Novartis] . . . from any civil or administrative monetary claim that the United States has or may have for the [specified drugs prior to December 31, 2009] under the False Claims Act, . . . any statutory provision creating a cause of action for civil damages or civil penalties . . . , or

> common law theories of fraud, payment by mistake, unjust enrichment, disgorgement of illegal profits and, if applicable, breach of contract.

(2010 Settlement Agreement (Dkt. No. 126) Ex. A to June 19, 2015 Gov't Ltr. ¶ 3)

By its plain language, the 2010 Settlement Agreement only releases claims and causes of action that the United States may have against Novartis with respect to certain Novartis drugs during the Release Period. The 2010 Settlement Agreement does not purport to limit discovery in any future litigation. Indeed, the 2010 Settlement Agreement does not mention discovery. Accordingly, the 2010 Settlement Agreement does not preclude the Government from seeking discovery – in a subsequent litigation – as to the drugs that are the subject of that agreement.

Moreover, the requested information for the 2002 to 2009 time period is relevant to the claims alleged in the Amended Complaint. With respect to Diovan, Tekturna, and Exforge, the Government alleges that – although it has released all claims prior to December 31, 2009 – "Novartis continued to conduct speaker programs on Diovan, Tekturna, and Exforge after December 31, 2009, through at least the end of 2011." (Am. Cmplt. (Dkt. No. 62) ¶ 173) The Amended Complaint identifies three specific instances of alleged misconduct during this period. See id. Data regarding speaker programs and prescription writing between 2002 and 2009 is relevant to the issue of whether post-2009 prescription writing was influenced by the speaker program. Moreover, it appears likely that much of the kickback activity occurring post-2009 began during the Release Period. Where kickback activity began during the Release Period and continued after it, the pre-2010 data is relevant to a determination of whether the prescriptions written in 2010 and beyond were the result of bribes paid by Novartis. For example, data from the Release Period could shed light on the state of mind of Novartis personnel and the prescribing doctors in the period after 2009, at least to the extent that the post-2009 conduct

mirrors earlier conduct. Accordingly, as to Diovan, Tekturna, and Exforge, the Government is entitled to the requested discovery material for the period between January 1, 2002 and December 31, 2009, because "the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. 26(b)(1).

With respect to Diovan HTC, Tekturna HTC, Exforge HTC, and Tekamlo, the Government alleges in the Amended Complaint that

> although . . . the September 2010 settlement released claims . . . for the drugs Diovan, Tekturna, and Exforge through December 31, 2009, the settlement, by its terms, did not release claims for Tekamlo or any of the HCT forms of these drugs. Numerous speaker programs occurred with respect to Tekamlo and the HCT forms of Diovan, Tekturna and Exforge throughout the time period relevant to this complaint.

(Id. ¶ 172) Novartis has not demonstrated that the 2010 Settlement Agreement bars kickback claims concerning the HCT Drugs and Tekamlo for the period between 2002 and 2009.

The Court concludes that the Government is entitled to the requested speaker program and prescription writing data as to all ten drugs at issue in this case for the period between January 1, 2002 and November 30, 2011.

B. Discovery of Pre-2002 and Post-November 2011 Data

The Government has also requested information about speaker programs and prescription writing for 2001 and for the period between December 1, 2011 and December 31, 2014. See June 19, 2015 Gov't Ltr. (Dkt. No. 126) at 2.

"[D]iscovery may not be used as a fishing expedition to discover additional instances of wrongdoing beyond those already alleged." Barbara, 2013 WL 1952308, at *2 (quotation marks and citation omitted). It "is meant to allow parties to flesh out allegations for which they initially have at least a modicum of objective support." Tottenham, 2002 WL 1967023, at *2 (quotation marks and citation omitted). The Government has not made any

allegations for the time period prior to January 1, 2002. With respect to the period after November 2011, the Amended Complaint alleges only that the illegal activity continued through "at least November 2011." (Am. Cmplt. (Dkt. No. 62) ¶ 1) The Amended Complaint contains no specific allegations of illegal conduct after November 2011, and the Government has not otherwise provided any "modicum of objective support" for any post-November 2011 claims. Tottenham, 2002 WL 1967023, at *2 (quotation marks and citation omitted).

In the context of the FCA, courts in other circuits have repeatedly found that rote allegations of "ongoing" illegal activity, unaccompanied by allegations of specific instances of wrongdoing, are insufficient to justify discovery beyond the time period during which specific instances of wrongdoing have been alleged. See U.S. ex rel. King v. Solvay S.A., No. H – 06 – 2662, 2013 WL 820498, at *3-4 (S.D. Tex. Mar. 5, 2013) (allegations of conduct "from 1996 to 2002 and beyond" and "from at least 1994 to the present" found insufficient "to justify the burden of discovery 'to the present'" (emphasis in original)); U.S. ex rel Spay v. CVS Caremark Corp., No. 09 Civ. 4672, 2013 WL 4525226, at *2-3 (E.D. Pa. Aug. 27, 2013) ("cursory allegations" that defendant "continue[d] to" pay out false claims beyond time period of specific allegations of misconduct "are unquestionably insufficient to open the door to broad and burdensome discovery" from 2006 to present, where complaint "extensively and repeatedly discusses the time period of January 1, 2006 through January 2008" and contains no allegations regarding post-January 2008). In sum, the requested discovery cannot be justified on the basis that it is necessary to "flesh out" the allegations of illegal activity during the pre-2002 and post-November 2011 period. Tottenham, 2002 WL 1967023, at *2 (quotation marks and citation omitted).

To justify discovery requests for documents generated outside the time period alleged in the Amended Complaint, the Government must demonstrate the relevance of the potential discovery to the claims it has asserted for the January 1, 2002 to November 30, 2011 time period. The Government merely speculates that the requested discovery may assist it in discovering information relevant to those claims, however. See June 19, 2015 Gov't Ltr. (Dkt. No. 126) at 4. In contrast to the 2002 to 2009 time period, the Government has not explained how information concerning Novartis's conduct before January 1, 2002 or after November 30, 2011 will lead to information relevant to the claims brought for the time period cited in the Amended Complaint. While the Government suggests that the additional years' worth of information increases the likelihood that relevant trends and fluctuations will become clear (see id.), discovery "is not boundless, and a court may place limits on discovery demands that are unreasonably cumulative or duplicative." Kingsway Fin. Servs., Inc., 2008 WL 4452134, at *4 (quotation marks and citation omitted).

Discovery in this case has been voluminous, with Novartis already having produced more than 2.6 million pages of documents. See April 23, 2015 Ltr. (Dkt. No. 124) at 2. As a result of this Order, Novartis will be required to produce approximately ten years' worth of speaker program and prescription writing data related to all ten of the drugs at issue. To the extent that trends and fluctuations in speaker program attendance and prescription writing exist, a decade's worth of data should be sufficient to demonstrate those trends and fluctuations. Given the extensive discovery that Novartis will be required to produce, and the fact that the Government has cited no specific instances of relevant conduct before 2002 or after November 30, 2011, "the burden or expense of the proposed discovery outweighs its likely benefit." Kingsway Fin. Servs., Inc., 2008 WL 4452134, at *4 (quotation marks and citation omitted).

Accordingly, Novartis will not be required to produce speaker program and prescription writing information for the time period prior to January 1, 2002 or after November 30, 2011.

CONCLUSION

For the reasons stated above, Novartis will produce the requested speaker program and prescription writing information as to all ten drugs at issue in this case for the time period between January 1, 2002 and November 30, 2011. Novartis is not required to produce the requested information for the time period prior to January 1, 2002 or after November 30, 2011.

The conference presently scheduled for July 29, 2015, is adjourned to November 12, 2015, at 10:00 a.m.

Dated: New York, New York
July 29, 2015

SO ORDERED.

Paul G. Gardephe
United States District Judge